UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

JEAN D. WRIGHT, Plaintiff, vs. DEPUY INC.; DEPUY INTERNATIONAL LIMITED; DEPUY IRELAND UNLIMITED COMPANY; DEPUY ORTHOPAEDICS, INC.; DEPUY MITEK, INC.; DEPUY SYNTHES, INC.; DEPUY SYNTHES JOHNSON & JOHNSON IRELAND LTD.; DEPUY SYNTHES PRODUCTS, INC.; DEPUY SYNTHES SALES, INC. D/B/A DEPUY SYNTHES JOINT RECONSTRUCTION; JOHNSON & JOHNSON; JOHNSON & JOHNSON INTERNATIONAL; JOHNSON & JOHNSON SERVICES, INC.; and MEDICAL DEVICE BUSINESS SERVICES, INC. Defendants.	:	Case No.: 3:19-cv-138 **COMPLAINT WITH JURY DEMAND**

COMPLAINT AND DEMAND FOR JURY TRIAL

COMES NOW, Plaintiff Jean D. Wright, by and through the undersigned counsel, and brings this Complaint against Defendants DePuy Inc.; DePuy International Limited; DePuy Ireland Unlimited Company; DePuy Orthopaedics, Inc.; DePuy Mitek, Inc.; DePuy Synthes, Inc.; DePuy Synthes Johnson & Johnson Ireland Ltd.; DePuy Synthes Products, Inc.; DePuy Synthes Sales, Inc. d/b/a DePuy Synthes Joint Reconstruction; Johnson & Johnson; Johnson & Johnson

International; Johnson & Johnson Services, Inc.; and Medical Device Business Services, Inc. (collectively, "Defendants"), and alleges as follows:

NATURE OF THE ACTION

1. This is an action for damages relating to Defendants' development, designing, testing, assembling, manufacturing, packaging, monitoring, labeling, preparing, distribution, marketing, supplying, and/or selling of the ATTUNE Knee System (hereinafter "ATTUNE" or "ATTUNE Device(s)").

2. Thousands of patients, like Plaintiff Jean D. Wright, have been and/or will be required to undergo extensive revision surgery to repair, remove and/or replace defective ATTUNE Devices. These revision surgeries have been necessitated, in part, by severe pain, swelling, and instability in the knee and leg caused by loosening, sliding or migration of ATTUNE's tibial baseplate component that results from debonding at the baseplate-cement interface. Patients implanted with ATTUNE Devices have also experienced fractures, infection, soft tissue injury and permanent damage to bones and nerves as a result of the failure of ATTUNE Devices.

3. Recipients of the ATTUNE Devices have been required to undergo revision surgeries well before the estimated life expectancy of the ATTUNE Devices and at a much higher rate than should reasonably be expected for devices of this kind.

4. Despite knowledge that the ATTUNE Devices were defective and resulted in the aforementioned failures and accompanying complications, Defendants continue to aggressively market and sell certain defective ATTUNE Devices, all the while maintaining that they are safe and effective for use in total knee replacements.

THE PARTIES

5. Plaintiff Jean D. Wright is a citizen of Ohio and resides in Butler County, Ohio. Plaintiff was implanted with a defective ATTUNE Device on October 31, 2016, which failed and resulted in a revision surgery on May 8, 2017 at Mercy Health Oxford Orthopaedics and Spine.

6. Defendant DePuy Synthes Sales, Inc. d/b/a DePuy Synthes Joint Reconstruction ("DSS") is and, at all times relevant, was a corporation organized and existing under the laws of the State of Massachusetts, with its principal place of business located at 325 Paramount Drive, Raynham, Massachusetts 02767, and regularly conducted business in the State of Ohio by selling and distributing its products in Ohio. Upon information and belief, DSS is a division and/or subsidiary of DePuy Orthopaedics, Inc. ("DOI"). DSS is a wholly-owned subsidiary of Johnson & Johnson, a publicly traded company.

7. DSS designs, makes, imports, distributes, sells and/or offers for sale total knee replacement prostheses, including the ATTUNE Device. DSS was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous orthopedic products, including the ATTUNE Device, as well as monitoring and reporting adverse events related to the ATTUNE Device.

8. Defendant Medical Device Business Services, Inc. ("Device Business Services") is and, at all times relevant, was a corporation organized and existing under the laws

of the State of Indiana, with its headquarters and principal place of business located at 700 Orthopaedic Drive, Warsaw, Indiana 46582, and regularly conducted business in the State of Ohio by selling and distributing its products in Ohio. Device Business Services is a wholly-owned subsidiary of Johnson & Johnson, a publicly traded company.

9. Defendant DePuy Orthopaedics, Inc. ("DOI") is and, at all times relevant, was a corporation organized and existing under the laws of the State of Indiana, with its headquarters and principal place of business located at 700 Orthopaedic Drive, Warsaw, Indiana 46582, and regularly conducted business in the State of Ohio by selling and distributing its products in Ohio. DOI is a wholly owned subsidiary of Johnson & Johnson, a publicly traded company.

10. At all times relevant, DOI and Device Business Services were engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, packaging, labeling and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous orthopedic products, including the ATTUNE Device, as well as monitoring and reporting adverse events associated with ATTUNE. DOI and Device Business Services participated in the decision-making process and response of the Defendants, if any, related to ATTUNE adverse events and/or MAUDE reports.

11. Defendant DePuy Synthes Products, Inc. ("DSP") is and, at all times relevant, was a corporation organized and existing under the laws of the State of Delaware with its principal place of business located at 325 Paramount Drive, Raynham,

Massachusetts 02767, and regularly conducted business in the State of Ohio by selling and distributing its products in Ohio.

12. DSP is division of DOI. DSP is a wholly-owned subsidiary of Johnson & Johnson, a publicly traded company.

13. Defendant DePuy Synthes, Inc. ("DS") is and, at all times relevant, was a corporation organized and existing under the laws of the State of Delaware with its principal place of business located at 700 Orthopaedic Drive, Warsaw, Indiana 46581, and at all relevant times was doing business in the State of Ohio by selling and distributing its products in Ohio.

14. Defendant DePuy Mitek, LLC ("DM") is and, at all times relevant, was a limited liability company organized and existing under the laws of the State of Massachusetts, with its principal place of business located at 325 Paramount Drive, Raynham, Massachusetts 02767, and regularly conducted business in the State of Ohio by selling and distributing its products in Ohio. DM operates as a subsidiary of DS, which is a wholly owned subsidiary of Johnson & Johnson, a publicly traded company.

15. DSP, DS, and DM design, manufacture, test, package, label, distribute, sell and/or offer for sale certain total knee replacement prostheses, including the ATTUNE Device.

16. Defendant DePuy, Inc. is and, at all times relevant, was a corporation organized and existing under the laws of the State of Delaware, with its headquarters and principal place of business at Corporation Trust Center, 1209 Orange Street,

Wilmington, Delaware 19801. At all relevant times, DePuy, Inc. conducted regular and sustained business in Ohio by selling and distributing its products in Ohio.

17. As DOI's parent company, DePuy, Inc. is and, at all relevant times, was involved in the business of designing, licensing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous orthopedic products, including the ATTUNE Device, as well as monitoring and reporting adverse events associated with ATTUNE. Upon information and belief, DePuy, Inc. participated in reviewing, investigating and/or responding to FDA adverse events and/or MAUDE reports related to the ATTUNE Device, and in the decision of whether to submit reports of ATTUNE failures to the FDA.

18. Defendant DePuy International, Ltd. ("DIL") is a public entity or corporation organized and existing under the laws of the United Kingdom, with its principal place of business at St. Anthony's Road, Beeston, Leeds, West Yorkshire, LS11 8DT, United Kingdom, and at all times relevant was doing business within the United States. At all relevant times, DePuy, International, Ltd. conducted regular and sustained business in Ohio by selling and distributing its products in Ohio.

19. DIL makes, designs, imports, distributes, labels, sells and/or offers for sale certain total knee replacement prostheses, including the ATTUNE Device.

20. DePuy Ireland Unlimited Company ("DePuy Ireland") is a company and a citizen of Ireland with its principal place of business located at Loughbeg Industrial Estate, Loughbeg Ringaskiddy, County Cork, Ireland, and at all relevant times was

doing business within the United States. At all relevant times, DePuy Ireland Unlimited Company conducted regular and sustained business in Ohio by selling and distributing its products in Ohio.

21. At all times relevant, DePuy Ireland was involved in the business of designing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly, through third parties or related entities, numerous orthopedic products, including the ATTUNE Device, as well as monitoring and reporting adverse events associated with ATTUNE. DePuy Ireland had a role in the decision-making process and response of the Defendants, if any, related to the handling of adverse events and MAUDE reports concerning ATTUNE Device failures.

22. DePuy Synthes Johnson & Johnson Ireland Ltd. ("Synthes Ireland") is an entity doing business and organized in Ireland with its principal place of business located at Unit 2, Block 10, Blanchardstown Corporate Park, Dublin 15, Ireland, and at all relevant times was doing business within the United States. At all relevant times, DePuy Synthes Johnson & Johnson Ireland Ltd. conducted regular and sustained business in Ohio by selling and distributing its products in Ohio.

23. At all times relevant, Synthes Ireland was involved in the business of designing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly, through third parties or related entities, numerous orthopedic products, including the ATTUNE Device, as well as monitoring and reporting adverse events associated with ATTUNE. Synthes Ireland had a role in the decision-making process and response of the Defendants, if any,

related to the handling of adverse events and/or MAUDE reports concerning ATTUNE Device failures.

24. Defendants DSS, DOI, DIL, DSP, DS, DM, DePuy, Inc., Device Business Services, DePuy Ireland and Synthes Ireland are collectively referred to as "DePuy" and the "DePuy Synthes Companies." The DePuy Synthes Companies are part of the Johnson & Johnson Family of Companies. The DePuy Synthes Companies are a group of functionally-integrated companies with shared management, administrative and general functions, including human resources, legal, quality control, customer service, sales administration, logistics, information technology, compliance, regulatory, finance and accounting and are considered a single business enterprise.

25. Defendant Johnson & Johnson International is and, at all times relevant, was a corporation organized and existing under the laws of the State of New Jersey with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933, and regularly conducted business in the State of Ohio by selling and distributing its products in Ohio.

26. As one of DePuy's parent companies, Johnson & Johnson International is and, at all relevant times, was involved in the business of designing, licensing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous orthopedic products, including the ATTUNE Device, as well as monitoring and reporting adverse events associated with ATTUNE. Johnson & Johnson International participated in the decision-making process and response, if any,

related to adverse events and/or MAUDE reports concerning the ATTUNE Device.

27. At all times material hereto, Defendant Johnson & Johnson ("J&J") is and was a public entity or corporation organized and existing under the laws of the State of New Jersey, with a principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933, and at all relevant times was doing business in the State of Ohio by selling and distributing its products in Ohio.

28. As DePuy's most senior parent company, Johnson & Johnson is and, at all relevant times, was involved in the business of designing, licensing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous orthopedic products, including the ATTUNE Device, as well as monitoring and reporting adverse events associated with ATTUNE. Johnson & Johnson participated in the decision-making process and response, if any, related to adverse events and/or MAUDE reports related to ATTUNE Device failures.

29. At all times material hereto, Defendant Johnson & Johnson Services ("J&J Services") was a public entity or corporation organized and existing under the laws of the State of New Jersey, with a principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933, and at all relevant times was doing business in the State of Ohio by selling and distributing its products in Ohio.

30. J&J Services is and, at all relevant times, was involved in the business of designing, licensing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third

parties or related entities, numerous orthopedic products, including the ATTUNE Device, as well as monitoring and reporting adverse events associated with ATTUNE. J&J Services participated in the decision-making process and response, if any, related to adverse events and/or MAUDE reports related to ATTUNE Device failures.

31. Plaintiffs have suffered personal injuries as a direct and proximate result of DePuy Synthes Sales, Inc. d/b/a/ DePuy Synthes Joint Reconstruction; Medical Device Business Services, Inc.; DePuy Orthopaedics, Inc.; DePuy Synthes Products, Inc.; DePuy Synthes, Inc.; DePuy Mitek, Inc.; DePuy, Inc.; DePuy International, Ltd.; DePuy Ireland Unlimited Company; DePuy Synthes Johnson & Johnson Ireland Ltd.; Johnson & Johnson International; Johnson & Johnson; and Johnson & Johnson Services Inc. (collectively "Defendants") conduct and misconduct, as described herein, in connection with the design, development, manufacturing, testing, packaging, advertising, marketing, distributing, labeling, warning and sale of the ATTUNE Device.

32. Defendant Johnson & Johnson is the parent company of Defendants DePuy International Limited, DePuy Ireland Unlimited Company and DePuy Synthes Johnson & Johnson Ireland Ltd.

33. Defendant Johnson & Johnson is the alter ego of wholly owned subsidiaries Defendants, DePuy International Limited; DePuy Ireland Unlimited Company and DePuy Synthes Johnson & Johnson Ireland Ltd ("subsidiary Defendants"). Defendant Johnson & Johnson has used these named subsidiary Defendants as its agents; and/or Defendant Johnson & Johnson and the named subsidiary Defendants are one

single integrated enterprise.

34. Defendants DePuy Ireland Unlimited Company and DePuy Synthes Johnson & Johnson Ireland Ltd. (hereinafter referred to as the "Ireland Defendants"), in addition to designing and manufacturing the ATTUNE Devices, were identified by the FDA as the manufacturer of failed ATTUNE Devices reported through the FDA's MAUDE system. Upon information and belief, the Ireland Defendants reported, and made decisions about whether or not to report failures of the ATTUNE Devices, which occurred within the United States, to the FDA.

35. Defendants DePuy International Limited; DePuy Ireland Unlimited Company and DePuy Synthes Johnson & Johnson Ireland Ltd. produced and disseminated misleading marketing publications throughout the United States, including Ohio, over-touting the safety and efficacy of the ATTUNE Device to consumers, hospitals and surgeons, including, but not limited to, the following marketing publications:

a. *The ATTUNE Knee System Value Analysis Brief*;[1]

b. A pamphlet titled "A Knee That Can Help You Get Back Sooner;"[2]

c. An article titled *Confidence in the ATTUNE Knee is Driven by Real World Scientific Responses to Inaccuracies and Limitations in Bonutti, et al. Article*, in which Defendants attempt to discredit the Bonutti paper which concluded that high rates of ATTUNE Device failures were occurring due to

[1] Available at http://synthes.vo.llnwd.net/o16/LLNWMB8/US%20Mobile/Synthes%20North%20America/Product%20Support%20Materials/Product%20Information%20Sheets/DSUSJRC05140188(1)%20ATTUNE%20Value%20Brief.pdf

[2] Available at http://synthes.vo.llnwd.net/o16/LLNWMB8/US%20Mobile/Synthes%20North%20America/Product%20Support%20Materials/Brochures/DSUS-JRC-0614-294_ATTUNE_Brochure_singles.pdf

debonding at the tibial baseplate-cement interface;[3]

d. An "ATTUNE Knee System Ordering Information" guide which catalogs component parts of the ATTUNE Device, which was designed for use and was used in the United States.[4]

36. Defendants DePuy International Limited; DePuy Ireland Unlimited Company and DePuy Synthes Johnson & Johnson Ireland Ltd. engaged in substantial business within the United States related to the ATTUNE Device, availed themselves of the benefits of conducting business in the United States and derived benefits from that business within the United States.

37. At all times relevant, each of the Defendants was the representative, agent, employee, co-conspirator, servant, employee, partner, joint-venture, franchisee, or alter ego of the other Defendants and was acting within the scope of such authority in such conspiracy, service, agency, employment, partnership, joint venture and/or franchise.

JURISDICTION AND VENUE

38. This Court has jurisdiction over this action under federal diversity jurisdiction, 28 U.S.C. § 1332, as the parties are completely diverse in citizenship and the amount in controversy exceeds $75,000, exclusive of costs and interest.

[3] Available at, http://synthes.vo.llnwd.net/o16/LLNWMB8/US%20Mobile/Synthes%20North%20America/Product%20Support%20Materials/Journal%20Articles/CERT%20ATTUNE%20WP%20Response%20to%20Bonutti.pdf

[4] Available at, http://synthes.vo.llnwd.net/o16/LLNWMB8/US%20Mobile/Synthes%20North%20America/Product%20Support%20Materials/Brochures/DSUSJRC11140570(2)%20ATTUNE%20Ordering%20Info.pdf

39. Venue in this district is proper under 28 U.S.C. § 1391 because a substantial part of the events giving rise to Plaintiff's claims occurred in the Southern District of Ohio, including the implantation of the defective ATTUNE Device, the revision surgery to repair the failed ATTUNE Device and the resulting injury.

40. Upon information and belief, Defendants regularly conduct business in the Southern District of Ohio. Defendants' commercial activities in the Southern District of Ohio include, without limitation, advertising, promotion, marketing and sale of the ATTUNE Devices.

FACTS

41. Total knee arthroplasty ("TKA"), also called total knee replacement ("TKR"), is a commonly performed orthopedic procedure. The surgery is designed to help relieve pain, to improve joint function, and to replace bones, cartilage and/or tissue that have been severely injured and/or worn down generally in people with severe knee degeneration due to arthritis, other disease or trauma. A TKA is ordinarily a successful orthopedic procedure with excellent clinical outcomes and survivorship.

42. In a total knee replacement surgery, sometimes referred to as "arthroplasty," physicians replace the joint surfaces and damaged bone and cartilage with artificial materials, such as the ATTUNE Device. The replacement redistributes weight and removes the tissue and/or bone causing inflammation, and thus reduces pain while improving the joint's function. Replacement requires a mechanical connection between the bones and the implant components.

43. DePuy Orthopaedics, Inc. was founded in 1895 and is purported to be a

worldwide leader in the design and manufacture of orthopedic devices and supplies, including hip, knee extremity, cement and other products used in orthopedic procedures.

44. According to DePuy, the ATTUNE Device "builds on the LCS Complete Knee System and the SIGMA Rotating Platform Knee," both of which are also DePuy products.

45. In 1977, DePuy Orthopaedics, Inc. introduced the LCS Complete Knee System which, at that time, included three options: a bi-cruciate-retaining option, a posterior cruciate retaining option, and a cruciate sacrificing option (the rotating-platform design).

46. DePuy introduced the P.F.C. Total Knee System in 1984. According to DePuy, clinical studies have proven the success of the P.F.C. design, with 92.6% survivorship at 15 years.

47. Based on this clinical success, according to DePuy, the company introduced the DePuy Synthes P.F.C. SIGMA System ("SIGMA") in 1996.

48. The SIGMA was one of the most widely used TKAs worldwide, and DePuy quickly became one of the largest manufacturers of knee replacement devices in the United States. According to DePuy, the SIGMA Fixed Bearing Knee System has demonstrated excellent survivorship with 99.6% at 7 years.

49. Notwithstanding DePuy's alleged success with the SIGMA, as reported by DePuy, the company began to tinker with the SIGMA design in an effort to replicate the total flexion of the natural knee and maintain a competitive position in the

market.

50. According to DePuy, the new ATTUNE project was an attempt to improve functional outcomes, provide more stability and simplify implantation of the contemporary total knee system.

51. The resulting ATTUNE total knee system purported to feature a gradually reducing femoral radius, an innovative s-curve design of the posteriorly stabilized cam, a tibial base which can be downsized or upsized two sizes versus the insert, novel patella tracking, lighter innovative instruments, and a new polyethylene formulation, according to DePuy. DePuy sought FDA clearance for the new ATTUNE Device through the "510(k)" process.

52. Section 510(k) of the Food, Drug and Cosmetic Act provides a mechanism for device manufacturers to obtain accelerated FDA clearance for products that are shown to be "substantially equivalent" to a product that has previously received FDA approval. The process requires device manufacturers to notify FDA of their intent to market a medical device at least 90 days in advance of introduction to the market. This is known as Premarket Notification – also called PMN or 510(k). This clearance process allows the FDA to determine whether the device is substantially equivalent to a device already approved for marketing.

53. By 2010, DePuy was ready to take the ATTUNE to market. In December 2010, DePuy Orthopaedics, Inc. received FDA clearance of the DePuy ATTUNE Knee System under the "510(k)" notification process. The basis for FDA clearance was substantial similarity to several prior devices, including, but not limited to, the P.F.C.

SIGMA Knee System. Consequently, Defendants received FDA clearance with only very limited, if any, testing of the new ATTUNE Device.

54. The ATTUNE Device includes the ATTUNE Tibial Base (510(k) Number K101433) ("ATTUNE tibial baseplate"), also called tibial tray, which, as compared to the SIGMA, included a design change to the keel, the surface texture and/or finish of the tibial baseplate and "combined with new technology to treat the underside of the implant," among other changes.

55. The FDA cleared the following specific medical device components as part of the DePuy ATTUNE Knee Total System:

a. The ATTUNE Cruciate Retaining (CR) Femoral Component;

b. The ATTUNE Fixed Bearing (FB) Tibial Inserts;

c. The ATTUNE Tibial Base, which is available in 10 sizes; and

d. The ATTUNE Patellae.

56. In August 2011, DePuy Orthopaedics, Inc. received 510(k) clearance for the DePuy ATTUNE Posterior Stabilized (PS) Femoral Components and PS Fixed Bearing inserts, which were additions to the existing DePuy ATTUNE Knee System. These components are compatible with the ATTUNE fixed tibial bases. This product was referred to as the DePuy ATTUNE PS Knee System.

57. The claims in this Complaint focus only on the ATTUNE Device as defined herein, which includes the DePuy ATTUNE Knee System (including its component parts) and the DePuy ATTUNE PS Knee System (including its component parts). The design and composition of the ATTUNE Device, especially the tibial baseplate,

is defective and failed resulting in harm to Plaintiff Jean D. Wright.

58. In March of 2013, DePuy and the J&J Defendants introduced its ATTUNE Device, including procedures for implantation, to surgeons and consumers. On March 20, 2013, DePuy issued a press release widely introducing its "latest innovation in total knee replacement—the ATTUNE Knee System—at the 2013 American Academy of Orthopedic Surgeons (AAOS) annual meeting in Chicago."

59. According to the press release, the ATTUNE Device was "designed to provide better range of motion and address the unstable feeling some patients experience during everyday activities, such as stair descent and bending." According to DePuy, its "proprietary technologies include: . . . SOFCAM Contact: An S-curve design that provides a smooth engagement for stability through flexion, while reducing stresses placed on the implant."

60. DePuy's launch strategy began with branding multiple "new" technologies and touting the project as one of the largest research and development projects in the history of the DePuy Synthes Companies, costing approximately $200 million. DePuy claimed the following features of the ATTUNE Device:

a. "Is the largest clinical program at DePuy,"

b. "Improves value of TKA,"

c. "Compares favorably in joint registries," and

d. "Significantly less symptomatic crepitus, primarily Sigma PS."

61. The most notable improvement Defendants purported to make between the SIGMA and ATTUNE is the patented S-curve design of the femoral component. This

feature, according to Defendants, conferred greater mid flexion stability as the implanted knee moves from extension to flexion because of the more gradual change in the femoral component radius of curvature. This design feature was also proposed to offer greater functional benefits and a greater range of movement as compared to other implants.

62. However, in reality, the ATTUNE Device did not deliver on these promises, resulting in significantly higher failure rates than previous DePuy knee counterparts due to the debonding, loosening and migration of the tibial baseplate and other components of the device. As a result, thousands of knee replacement patients implanted with ATTUNE Devices have had more expensive, more dangerous and less effective Total Knee Replacement surgeries, and many have required or will require expensive and dangerous knee revision surgery to repair, remove and/or replace the defective ATTUNE Devices.

63. Since the initial launch, Defendants have continued to expand the ATTUNE product line based on claims it would provide patients who were "expecting to maintain an active lifestyle" a more life-like knee. Defendants have aggressively marketed the ATTUNE Device and became the dominant player in the knee market, upon information and belief, selling approximately 400,000 ATTUNE Devices worldwide.

64. The primary reason the ATTUNE Device fails is mechanical loosening, sliding, migration or a lack of long-term fixation. The mechanical loosening, sliding or migration is caused by a failure of the bond between the tibial baseplate at the

implant-cement interface, or a mechanical mismatch of poorly designed device component marketed as replicating the human anatomy. Mechanical loosening, sliding, migration or the mechanical mismatch means that the attachment between the artificial knee and the existing bone has become loose, migrated or lacks long-term fixation. Such loosening will eventually result in failure of the device and other complications, including severe pain. Mechanical loosening, lack of long-term fixation and migration has occurred at an unprecedented and unacceptable rate in patients implanted with an ATTUNE Device.

65. In many instances, loosening or migration of an artificial knee can be visualized and diagnosed using radiographic imaging. The loosening can be evident in certain cases from one or more radiolucent lines around the contours of the artificial knee component where the loosening is occurring.

66. The loosening, migration and/or lack of long-term fixation can be visualized by the surgeon revising the defective and failed ATTUNE Device and is often noted in the operative reported accompanying a failed and defective ATTUNE Device.

67. A loose artificial knee and/or loose tibial components generally cause severe pain and wearing away of the bone and surrounding tissue. It can severely restrict a patient's daily activities as it can involve a severe physical and emotional burden for the patient.

68. Once the pain becomes unbearable or the individual loses function of the knee, another operation, often times called a "revision surgery," may be required to repair or remove the knee implant and replace it with a new one.

69. Unfortunately, a failed total knee prosthesis often causes severe bone loss, excessive scarring and damage to the surrounding tissue. Therefore, revision surgeries on a failed total knee due to loosening, migration and lack of long-term fixation often require reconstruction of the severe bone loss and increase the risk of additional failures in the future, chronic pain and immobility.

70. The success rate of a revision surgery is much lower than that of the initial total knee replacement and the risks and complications are higher, including, but not limited to, limitations in range of motion, the ability to walk, and even death.

71. Beginning in 2013 and 2014, Defendants became aware of safety issues with the ATTUNE Device. These concerns were evidenced through failure reports submitted to and kept in the FDA's Manufacturer and User Facility Device Experience (MAUDE), which houses medical device reports submitted to the FDA by reporters such as manufacturers, importers and device user facilities. Most related reports concern failures caused by ATTUNE Device design elements which caused loosening, lack of long-term fixation, migration and/or debonding at the tibial baseplate cement/implant interface or related components. These MAUDE reports detail an extremely high incidence of aseptic loosening at the tibial baseplate of the ATTUNE Device resulting in subsequent revision surgeries.

72. Upon information and belief, the FDA MAUDE database, as of June 2017, includes approximately 1,400 reports of failures. Approximately 633 of these reports resulted in revision surgeries. By comparison, for the Persona knee replacement system, manufactured by Zimmer, approximately 384,000 devices have been

implanted, and the MAUDE database has a collection of only 183 reports of device failures with 64 of these resulting in revision surgeries.

73. On March 15, 2017, DePuy Synthes, at the American Academy of Orthopaedic Surgeons ("AAOS") Annual Meeting in San Diego, California, announced the launch of the first ATTUNE Knee revision system, which included the ATTUNE Revision Fixed Bearing Tibial Base and a 14 x 50 mm Cemented Stem.

74. Ostensibly, noticing the alarming rate of failure and subsequent revisions related to the ATTUNE Device, on March 10, 2016, DePuy Orthopaedics, Inc. submitted a Section 510(k) premarket notice of intent to market the "ATTUNE Revision Knee System," which included a new stem, with added length and a keel for additional stability and recessed cement pockets intended to promote cement fixation, attempting to alleviate the defective mechanical mismatch design of the ATTUNE device and rectify the unacceptable failures and revisions due to the loosening, lack of long-term fixation and migration of the components of the device, specifically the tibial components. The stem of the ATTUNE Revision Knee System was designed with a cylindrical or tapered body geometry with a blasted and fluted fixation surface.

75. Without notifying consumers, doctors or patients, including Plaintiff and her physicians, Defendants recently attempted to replace the original ATTUNE Fixed Base tibial baseplate with a new tibial baseplate, which received FDA 510(k) clearance on June 15, 2017. This strategic decision to design and launch a newly designed tibial baseplate is an acknowledgment of the defective and unsafe nature of the ATTUNE, or at the very least strong evidence, that the original ATTUNE Tibial

Tray (baseplate) is defective and prone to failure. However, Defendants have not recalled the defective ATTUNE, nor the defective tibial baseplate components, or informed consumers and surgeons about the dangers of its use.

76. Defendants requested FDA approval of the new tibial baseplate by application dated March 17, 2017 which was "prepared" by Defendants on March 16, 2016. The application requested clearance of a new tibial baseplate component as part of the ATTUNE Knee Total System, which, upon information and belief, has been called the "ATTUNE S+ Technology" ("ATTUNE S+") by Defendants. In particular, the application identified the design changes that were implemented with the ATTUNE S+, including a newly designed "keel to provide additional stability," "recessed undercut cement pockets," and a "grit blasted surface for enhanced cement fixation" or micro-blast finish.

77. The "Summary of Technologies" portion of the 510(k) application for the ATTUNE S+ tibial baseplate includes the following:

> The ATTUNE Cemented Tibial Base, FB provides a macro geometric feature and an optimized micro-blast finish which are both intended to aid in fixation of the tibial implant to the bone cement. The ATTUNE Cemented Tibial Base, FB is designed to enhance fixation by improving resistance (relative to the industry) to intra-operative factors which result in a reduction in cement to implant bond.

78. Additionally, according to DePuy, the ATTUNE S+ tibial baseplate also features macro geometry and 45 degree undercut pockets designed to provide a macro-lock between the cement-implant interface. According to DePuy, the "ATTUNE S+ Technology finishing process increases the surface roughness compared with other, DePuy Synthes clinically proven, tibial tray designs that were tested."

79. Defendants knew about the design defects and resulting failures with the original ATTUNE, and the ATTUNE tibial baseplate components, long before the newly designed tibial baseplate (ATTUNE S+) was cleared in June of 2017, yet they failed to share this information with orthopedic surgeons using the ATTUNE devices. In fact, the application for approval for the ATTUNE S+ was submitted by DePuy to the FDA on March 16, 2016, and many surgeons are still in the dark about Defendants abandoning the original ATTUNE design and the replacement ATTUNE design.

80. By March 16, 2016 or before, Defendants had apparently recognized the existence of high failure rates of the original ATTUNE and ATTUNE tibial baseplate, identified the defects and/or mechanisms of failure associated with it, researched and designed the new tibial tray/baseplate (ATTUNE S+), conducted testing of this new tibial baseplate, as detailed in the application, and submitted the application to the FDA.

81. Upon information and belief, Defendants were also communicating, conspiring and concealing the safety issues and unacceptable safety defects with the original ATTUNE as early as 2013 or before.

82. Although Defendants obviously knew about the high number of ATTUNE failures resulting in revision surgeries, it failed to warn surgeons, consumers and patients, and allowed the original, defective design to continue to be implanted by unsuspecting surgeons into unsuspecting patients, including Plaintiff and Plaintiff's physicians.

83. In fact, beginning in December 2016, DePuy began openly admitting, in its responses in the MAUDE failure reports, that the ATTUNE Devices were failing. Although DePuy decided to make a change, it did not inform the surgeons, consumers and/or patients. In responding to the MAUDE reports involving failures of ATTUNE tibial baseplates, DePuy frequently provided the following "Manufacturer Narrative":

> The information received will be retained for potential series investigations if triggered by trend analysis, post market surveillance or other events within the quality system. (b)(4) has been undertaken to investigate further. *The analysis and investigations eventually led to a new product development project, which will enhance fixation and make the product more robust to surgical technique per co (b)(4).* Depuy considers the investigation closed at this time. Should the additional information be received, the information will be reviewed, and the investigation will be re-opened as necessary.

84. In January of 2017, the Journal of Arthroplasty published a study, led by Dr. Raymond H. Kim and other surgeons at Colorado Joint Replacement, Department of Orthopedic Surgery, and OrthoCarolina, Department of Orthopaedic Surgery entitled Tibial Tray Thickness Significantly Increases Medial Tibial Bone Resorption in Cobalt-Chromium Total Knee Arthroplasty Implants. The study reported that the thicker cobalt-chromium baseplate of the ATTUNE Device was associated with significantly more tibial bone loss.

85. During the AAOS Annual Meeting in March 2017, Dr. Todd Kelley, Assistant Professor of Orthopaedic Surgery at the University of Cincinnati College of Medicine, presented a poster entitled High Incidence of Stress Shielding and Radiolucent Lines with a Novel Total Knee System, which involved a study of the ATTUNE Device.

86. The evaluators acknowledged that a relationship between stress shielding and bone resorption leading to aseptic loosening and implant failure existed.

Consequently, the purpose of the study was to determine the incidence of radiographic stress shielding and radiolucent lines in the tibia and femur during the early postoperative period following the implant of an ATTUNE Device.

87. As part of this study, 164 patients underwent a total knee replacement with the ATTUNE Device between February 2013 and February 2015. The mean length of the postoperative radiographic follow up was eight months. For all evaluators in the study, stress shielding was most frequently identified at the same three zones, with the highest incidence at "tibial AP zone 1," which was the medial baseplate. The incidence rate at this zone was 39.0%-48.5%.

88. The findings also demonstrated that the mean incidence rate of stress shielding at the tibial AP zone 1 among all evaluators was 43.1% and the mean incidence rate of radiolucent lines observed at this zone was 12.0%. These rates far exceed the rate expected in the post-surgery period.

89. In 2017, the alarming rate of failure associated with the ATTUNE Device due to debonding, loosening, and migration of the tibial baseplate was discussed in a paper written by Dr. Peter M. Bonutti and colleagues, entitled Unusually High Rate of Early Failure of Tibial Component in ATTUNE Total Knee Arthroplasty System at Implant-Cement Interface. The article presented compelling evidence that the design and/or composition of the ATTUNE Device, and particularly the tibial baseplate component, contribute greatly to debonding or lack of long-term fixation at the interface between the cement and the tibial baseplate, resulting in high rates of failure and revision surgery.

90. The authors' intraoperative findings identified freely mobile tibial baseplates with loosening occurring at the implant-cement interface. In all tibial baseplate failures in the study, the tibial component had deboned and was easily separated from the cement mantle, while all the cement was strongly adherent to the tibial bone. On the femoral side, however, the cement was strongly adherent to the implant surface in all cases. The mean time to revision for those ATTUNE Devices involved in the study was 19 months.

91. The authors of the Bonutti study concluded that high rates of ATTUNE failures due to debonding at the tibial-cement interface could be caused by a combination of factors, including the increased constraint of the ATTUNE's tibial polyethylene component; rounded edges and reduced cement pockets necessary for cement interdigitation in the tibia, as compared to the DePuy SIGMA; reduced keel rotational flanges and/or stabilizers on the keel; and insufficient surface roughness of the tibial baseplate component.

92. The Defendants began a campaign immediately, communicating, first internally, on how to attack the data now being made public about the lack of safety with the ATTUNE device and how to smear those who would alert the public as to the lack of safety with the ATTUNE device, and, subsequently, spreading innuendo and press releases to smear, attack and undermine the data being made public for the first time regarding the serious defective nature of the ATTUNE device and the mechanical mismatch component design of the device.

93. Despite Defendants' claim that the ATTUNE Device would be easier to

implant, after being notified of premature tibial baseplate failures, Defendants began blaming implanting surgeons and their surgical technique for the failures of the ATTUNE tibial baseplates rather than the ATTUNE's defects, which Defendants knew existed long ago, and using consultants of the company to attack and undermine safety reports and falsely reassure any fears or concerns the public had.

94. According to Defendants, the ATTUNE Device produces better stability of the knee in deep flexion, reduces the joint forces, and produces better patella tracking, operative flexibility and efficiency, and implant longevity. Defendants aggressively marketed the ATTUNE based on these assertions. Despite these claims, large numbers of revision cases appeared in a short period resulting from the defects in the ATTUNE tibial baseplate.

95. Patients were promised they could recover faster and engage in more active lifestyles. Contrary to Defendants' representations, however, the ATTUNE Device is prone to failure, causing patients to experience additional pain and injury.

96. Defendants designed, manufactured, tested, labeled, packaged, distributed, supplied, marketed, advertised, and/or otherwise engaged in all activities that are part of the sale and distribution of medical devices, and by these activities, caused ATTUNE Devices to be placed into the stream of commerce throughout the United States and within Ohio.

97. Defendants actively and aggressively marketed to doctors and the public that the ATTUNE Devices were safe and effective total knee prostheses.

98. From the time that Defendants first began selling ATTUNE Devices, the

product labeling and product information for the ATTUNE Device failed to contain adequate information, instructions, and warnings concerning the increased risk that the ATTUNE Device fails at an extremely high rate.

99. Despite Defendants' knowledge of the serious injuries associated with the use of the ATTUNE Device, Defendants continue to engage in marketing and advertising programs which falsely and deceptively create the perception that the ATTUNE Device is safe.

100. Upon information and belief, Defendants downplayed the health risks associated with the ATTUNE Device through promotional literature and communications with orthopedic surgeons. Defendants deceived doctors, including Plaintiff's surgeons, and potential users of the ATTUNE Device by relaying positive information, while concealing the nature and extent of the known adverse and serious health effects of the ATTUNE.

101. Based on the design changes made to the original ATTUNE tibial baseplate before it was put on the market, and the number of failures reported since it was launched, Defendants, through their pre- and post-marketing analysis, knew or should have known that the ATTUNE Device was prone to fail. Plaintiff alleges that the ATTUNE Device is defective and unreasonably dangerous.

102. Defendants represented to consumers the ATTUNE Knee System had undergone extensive research and testing to improve outcomes for patients, would relieve pain and restore function and mobility for arthritis pain sufferers, over 90% of patients had successful outcomes at 15 years, saved patients and society money

due to reduced disability costs and improved productivity after receiving the ATTUNE, was designed to deliver a "high level of stability" and "minimized unnatural sliding," was uniquely designed to deliver "optimal wear resistance" and long-term stability, was designed to address stability, prevent loosening or sliding and closely match motion and stability found in the native knee anatomy, reduced the risk of soft tissue irritation and tracking complications, was similar to the native knee functions, and, was specifically designed to address one of the most common complaints after knee replacement surgery, pain.

103. These claims were unfounded, lacked reliable scientific support, downplayed and concealed the design deficiencies of the device, and Defendants were on notice these claims were false and misleading.

104. On or about October 31, 2016, Plaintiff underwent a total knee replacement surgery at Mercy Health Oxford Orthopaedics and Spine in Oxford, Ohio. Plaintiff was implanted with an ATTUNE Device, including, but not limited to, a fixed tibial insert and a fixed tibial baseplate, which was designed, manufactured, marketed, distributed, labeled and sold throughout the United States by Defendants.

105. After the ATTUNE Device was implanted, Plaintiff began to experience sever and persistent pain, discomfort, instability and difficulty ambulating caused by the aseptic loosening, debonding and migration of the defective tibial baseplate.

106. On May 8, 2017, Plaintiff underwent revision surgery to repair the defective ATTUNE Device implanted in her knee due to the lack of bond and/or long-term

fixation, loosening and failure of the implant. This surgery was performed by Dr. Brian Rottinghaus at Mercy Health Oxford Orthopaedics and Spine.

107. Dr. Rottinghaus diagnosed Plaintiff with a "failed tibial component."

108. Neither Plaintiff nor her physicians were aware, by warning or otherwise, of the defect in the ATTUNE Device or excessive risks due to the unique design flaws of the ATTUNE Device, and would not have used the ATTUNE Device had they been aware of the defective nature of the device.

109. As a direct and proximate result of the Defendants placing the defective ATTUNE Device in the stream of commerce, Plaintiff has suffered and continues to suffer both injuries and damages, including, but not limited to, past, present and future physical and mental pain and suffering; and past, present and future medical, hospital, rehabilitative and pharmaceutical expenses; economic damages; and other related damages.

COUNT I
(STRICT PRODUCTS LIABILITY—MANUFACTURING DEFECT)

110. Plaintiff re-alleges and incorporates, as if fully rewritten, every allegation contained in the preceding paragraphs.

111. Defendants designed, manufactured, marketed and transferred the ATTUNE Device in the course of its business into the stream of commerce.

112. The ATTUNE Device surgically implanted in Plaintiff was in a defective condition unreasonably dangerous in its manufacture when it left the hands of Defendants in that it deviated from product specifications, posing a serious risk it could fail early in patients, could cause debonding, fractures, infection, soft tissue

injury and permanent damage to bones and nerves surrounding the knee joint and, therefore, give rise to physical injury, pain and suffering, debilitation, and the need for revision surgery to repair and/or replace the device with the attendant risks of complications and death from such further surgeries.

113. At all times relevant hereto, the ATTUNE Device failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

114. As a direct and proximate result of Defendants' transfer of the defective ATTUNE Device into the stream of commerce, Plaintiff has suffered and will continue to suffer significant damages, including, but not limited to, partial or complete loss of mobility, loss of range of motion and other severe and personal injuries which are permanent and lasting, physical pain and mental anguish, including diminished enjoyment of life and the need for revision surgeries to repair and/or replace the device with the attendant risks of complications and death from such further surgeries.

115. When Defendants sold the ATTUNE Device for implantation in Plaintiff, Defendants knew of the defective condition and danger and showed complete indifference to and a conscious disregard for the health and safety of others, including Plaintiff, entitling Plaintiff to punitive damages to punish Defendants and to deter Defendants and others from similar conduct.

COUNT II
(STRICT PRODUCTS LIABILITY—DESGN DEFECT)

116. Plaintiff re-alleges and incorporates, as if fully rewritten, every allegation contained in the preceding paragraphs.

117. The ATTUNE Device researched, designed, manufactured, tested, marketed, sold and/or distributed by Defendants were in an unsafe, defective, and inherently dangerous condition, which was dangerous to users such as Plaintiff.

118. The ATTUNE Device was expected to and did reach the usual consumers, handlers and persons, including Plaintiff, coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed and marketed by Defendants.

119. At all relevant times, the ATTUNE Device researched, designed, manufactured, tested, advertised, promoted, sold and/or distributed by Defendants was in an unsafe, defective, and inherently dangerous condition when it left Defendant's possession and entered the stream of commerce. As designer, manufacturer, and/or seller of such medical devices, Defendants had a duty to design, manufacture, and sell devices that would not cause harm to users, including Plaintiff.

120. The ATTUNE Device's unsafe, defective, and inherently dangerous condition was the cause of the injuries to Plaintiff.

121. At all times relevant hereto, the ATTUNE Device failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

122. The ATTUNE Device is defective in design because of the tibial baseplate's propensity to loosen and cause patients unnecessary pain, failure of the device and

repeat surgical procedures, including revision surgeries, resulting in additional bone loss and other complications.

123. Defendants were aware of the defects in design of the ATTUNE Device, in particular the ATTUNE tibial baseplate, as Defendants recently redesigned and obtained approval of the ATTUNE S+ tibial baseplate which includes features designed to correct the fixation problems caused by the original ATTUNE tibial baseplate which was implanted into Plaintiff.

124. Plaintiff is and was a foreseeable user of the ATTUNE Device.

125. Plaintiff was not able to discover, nor could she have discovered through the exercise of reasonable care, the defective nature of the ATTUNE Device. Further, in no way could Plaintiff have known that Defendants had designed, developed and manufactured the ATTUNE Device in a way as to make the risk of harm or injury outweigh any therapeutic benefits.

126. The ATTUNE Device is and was used in the Defendants' intended manner at the time that it was surgically implanted into Plaintiff.

127. Defendants had a duty to create a product that was not unreasonably dangerous for its normal intended use and breached this duty.

128. Defendants knew or should have known that the ATTUNE Device would be implanted in patients and that physicians and patients were relying on Defendants to furnish a suitable product.

129. Defendants knew and foresaw or should have known or foreseen that patients in whom the ATTUNE Devices would be implanted, such as Plaintiff, could be and

should have been affected by the defective design and composition of the ATTUNE Device.

130. Defendants designed, researched, manufactured, advertised, promoted, marketed, sold and/or distributed a defective product which, when used in its indented or reasonably foreseeable manner, created an unreasonable risk to the health of consumers and to Plaintiff specifically; therefore, Defendants are strictly liable for the injuries sustained by Plaintiff.

131. As a direct and proximate result of Defendants' placement of the defective ATTUNE Device into the stream of commerce, Plaintiff suffered and will continue to suffer significant damages, including, but not limited to, partial or complete loss of mobility, loss of range of motion and other severe and personal injuries which are permanent and lasting, physical pain and mental anguish, including diminished enjoyment of life and the need for revision surgeries to repair and/or replace the device with the attendant risks of complications and death from such further surgeries.

132. When Defendants sold the ATTUNE Device for implantation in Plaintiff, Defendants knew of the defective condition and danger and showed complete indifference to and a conscious disregard for the health and safety of others, including Plaintiff, entitling Plaintiff to punitive damages to punish Defendants and to deter Defendants and others from similar conduct.

133.

COUNT III
(STRICT PRODUCTS LIABILITY—INADEQUATE WARNING)

134. Plaintiff re-alleges and incorporates, as if fully rewritten, every allegation contained in the preceding paragraphs.

135. Defendants designed, manufactured, marketed and transferred the ATTUNE Device in the course of its business into the stream of commerce.

136. The ATTUNE Device surgically implanted in Plaintiff was in a defective condition unreasonably dangerous in its manufacture when it left the hands of Defendants in that it deviated from product specifications, posing a serious risk it could fail early in patients, could cause debonding, fractures, infection, soft tissue injury and permanent damage to bones and nerves surrounding the knee joint and, therefore, give rise to physical injury, pain and suffering, debilitation, and the need for revision surgery to repair and/or replace the device with the attendant risks of complications and death from such further surgeries.

137. At all times relevant hereto, the ATTUNE Device failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

138. When Defendants placed the ATTUNE Device into the stream of commerce for implantation in Plaintiff, Defendants knew of the defective condition and danger but failed to warn of the material facts regarding the safety and efficacy of the ATTUNE Device. Had they done so, proper warnings would have been heeded and no healthcare professional, including Plaintiff's physicians, would have used the ATTUNE Device, and no consumer, including Plaintiff, would have purchased and/or used the ATTUNE Device.

139. Defendants' acts and omissions constitute an adulteration, misbranding, or both, as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331 and 333, and constitute a breach of duty, subjecting Defendants to civil liability for all damages arising therefrom.

140. Furthermore, Defendants failed to comply with the FDA's Medical Device Reporting regulations requiring a manufacturer of a device to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in such a way that would likely cause or contribute to death or serious injury if the malfunction recurred. 21 U.S.C. § 360i(a)(1); 21 C.F.R. § 803.50(a).

141. As a direct and proximate result of Defendants' placement of the defective ATTUNE Device into the stream of commerce and failure to comply with federal requirements, Plaintiff has suffered and will continue to suffer significant damages, including, but not limited to, partial or complete loss of mobility, loss of range of motion and other severe and personal injuries which are permanent and lasting, physical pain and mental anguish, including diminished enjoyment of life and the need for revision surgeries to repair and/or replace the device with the attendant risks of complications and death from such further surgeries.

COUNT IV
(BREACH OF EXPRESS WARRANTY)

142. Plaintiff re-alleges and incorporates, as if fully rewritten, every allegation contained in the preceding paragraphs.

143. Defendants designed, manufactured, marketed and transferred the ATTUNE Device in the course of its business into the stream of commerce.

144. Defendants expressly warranted the ATTUNE Device was a safe and effective knee replacement system, along with aforementioned claims and warranties, and these express warranties and representations were material factors inducing Plaintiff to purchase the ATTUNE Device for implantation in Plaintiff's knee.

145. The ATTUNE Device was defective in that when it left the Defendants' hands, it did not conform to Defendants' representations.

146. Plaintiff justifiably relied on Defendants' express warranties and representations regarding the safety of the ATTUNE Devices.

147. As a direct and proximate result of Defendants' placement of the defective ATTUNE Device into the stream of commerce and Plaintiff's use of the defective ATTUNE Device as designed, manufactured, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff has suffered and will continue to suffer significant damages, including, but not limited to, partial or complete loss of mobility, loss of range of motion and other severe and personal injuries which are permanent and lasting, physical pain and mental anguish, including diminished enjoyment of life and the need for revision surgeries to repair and/or replace the device with the attendant risks of complications and death from such further surgeries.

COUNT V
(BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY)

148. Plaintiff re-alleges and incorporates, as if fully rewritten, every allegation contained in the preceding paragraphs.

149. Defendants designed, manufactured, marketed and transferred the ATTUNE Device in the course of its business into the stream of commerce.

150. When Defendants designed, manufactured, marketed and distributed into the stream of commerce the ATTUNE Device, Defendants, knowing the use for which the ATTUNE Device was intended, impliedly warranted the ATTUNE Device to be of merchantable quality and safe for such use.

151. Plaintiff justifiably relied on Defendants' skill and judgment whether the ATTUNE Device was of merchantable quality and safe for its intended use.

152. Contrary to Defendants' implied warranties, the ATTUNE Device was not of merchantable quality or safe for its intended use because it was unreasonably dangerous and in a condition dangerous to users such as Plaintiff in that the ATTUNE Device could fail early in patients and could cause debonding, fractures, infection, soft tissue injury and permanent damage to bones and nerves surrounding the knee joint and, therefore, give rise to physical injury, pain and suffering, debilitation, and the need for revision surgeries to repair and/or replace the device with the attendant risks of complications and death from such further surgeries.

153. As a direct and proximate result of Defendants' breach of implied warranties regarding the safe and effective nature of the ATTUNE Device, Plaintiff has suffered and will continue to suffer significant damages, including, but not limited to, partial or complete loss of mobility, loss of range of motion and other severe and personal injuries which are permanent and lasting, physical pain and mental anguish, including diminished enjoyment of life and the need for revision surgeries to repair and/or replace the device with the attendant risks of complications and death from such further surgeries.

COUNT VI
(NEGLIGENCE)

154. Plaintiff re-alleges and incorporates, as if fully rewritten, every allegation contained in the preceding paragraphs.

155. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control, and/or distribution of the ATTUNE Device into the stream of commerce, including a duty to assure that the ATTUNE Device would not cause those who had it surgically implanted to suffer adverse harmful effects from it.

156. Defendants failed to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control, and/or distribution of the ATTUNE Device into the stream of commerce in that Defendants knew or should have known those individuals who had the device surgically implanted were at risk for suffering harmful effects from it, including, but not limited to, partial or complete loss of mobility, loss of range of motion and other severe and personal injuries which are permanent and lasting, physical pain and mental anguish, including diminished enjoyment of life and the need for revision surgeries to repair and/or replace the ATTUNE Device with the attendant risks of complications and death from such further surgeries.

157. The negligence of Defendants, their agents, servants and/or employees includes, but is not limited to, the following acts and/or omissions:

a. Designing the ATTUNE Device in a manner dangerous to those individuals who had the device surgically implanted;

b. Designing, manufacturing, producing, creating, and/or promoting the ATTUNE Device without adequately, sufficiently or thoroughly testing it;

c. Designing, researching, developing, manufacturing, marketing, promoting and selling a medical device when it knew or should have known of the unacceptable risk of loosening, sliding, migration, lack of long-term fixation and early failure;

d. Not conducting sufficient testing to determine whether the ATTUNE Device was safe for use;

e. Selling the ATTUNE Device without making proper and sufficient tests to determine the dangers to its users;

f. Failing to adequately and correctly warn Plaintiff or her physicians, hospitals and/or healthcare providers of the dangers of the ATTUNE Device;

g. Providing inaccurate labeling and inadequate warnings and instructions with the ATTUNE Device;

h. Advertising and recommending the use of the ATTUNE Device although Defendants knew or should have known of its dangerous nature and propensities;

i. Under-reporting, underestimating and downplaying the serious danger of the ATTUNE Device to the public and to healthcare professionals to which it marketed and sold the ATTUNE Device;

j. Continuing to produce and sell the ATTUNE Device given the propensity of the device to fail;

k. Failing to recall the defective ATTUNE Device at the earliest date that it became known or should have become known to Defendants that the ATTUNE Device was dangerous and defective; and

l. Other breaches and defects which may be proven through discovery or at trial.

158. Defendants knew or should have known that consumers such as Plaintiff would suffer foreseeable injury, and/or be at an increased risk of suffering injury because of Defendants' failure to exercise ordinary care.

159. Defendants' negligence was the proximate cause of Plaintiff's physical, mental and emotional injuries and harm which she suffered and will continue to suffer in the future.

160. The conduct of Defendants as described showed complete indifference to and conscious disregard for the health and safety of others, including Plaintiff, entitling Plaintiff to punitive damages to punish and deter Defendants and others from similar conduct.

COUNT VII
(NEGLIGENT MISREPRESENTATION)

161. Plaintiff re-alleges and incorporates, as if fully rewritten, every allegation contained in the preceding paragraphs.

162. Defendants supplied false information to the public, to Plaintiff, and to the physicians that implanted the ATTUNE Device regarding the quality, safety and effectiveness of the ATTUNE Device. Defendants provided this false information to

induce the public, including Plaintiff and Plaintiff's physicians, to purchase and implant ATTUNE Devices.

163. Defendants knew or should have known that the information they supplied regarding the quality, safety and effectiveness of the ATTUNE Device was false.

164. Defendants were negligent in obtaining or communicating false information regarding the quality, safety and effectiveness of the ATUNE Devices.

165. Plaintiff relied on the false information supplied by Defendants to Plaintiff's detriment.

166. Plaintiff was justified in her reliance on the false information supplied by Defendants regarding the quality, safety and effectiveness of the ATTUNE Device.

167. As a direct and proximate cause of Defendants' negligent misrepresentations, Plaintiff suffered and will continue to suffer significant damages, including, but not limited to, partial or complete loss of mobility, loss of range of motion and other severe and personal injuries which are permanent and lasting, physical pain and mental anguish, including diminished enjoyment of life and the need for revisions surgeries to repair and/or replace the device with the attendant risks of complications and death from such further surgeries.

COUNT VIII
(FRAUD)

168. Plaintiff re-alleges and incorporates, as if fully rewritten, every allegation contained in the preceding paragraphs.

169. Defendants made representations to Plaintiff and her physicians that the ATTUNE Device was a high quality, safe and effective knee replacement system.

170. Defendants knew or should have known that the information they supplied regarding the quality, safety and effectiveness of the ATTUNE Device was false.

171. Defendants concealed their knowledge of the unreasonable risks and dangers associated with the ATTUNE Device to induce Plaintiff and many thousands of other patients to purchase the ATTUNE Device for surgical implantation into their bodies.

172. Plaintiff did not know the falsity of Defendants' statements regarding the ATTUNE Device.

173. Plaintiff relied on the false information supplied by Defendants to Plaintiff's detriment.

174. Plaintiff was justified in her reliance on the false information supplied by Defendants regarding the quality, safety and effectiveness of the ATTUNE Device.

175. Had Plaintiff known that the ATTUNE Device would fail early and expose Plaintiff to the unreasonable risk of device failure, including the need for additional revision surgeries, Plaintiff would not have purchased or allowed the ATTUNE Device to be surgically implanted into her body.

176. As a direct and proximate cause of Defendants' fraudulent misrepresentations, Plaintiff suffered and will continue to suffer significant damages, including, but not limited to, partial or complete loss of mobility, loss of range of motion and other severe and personal injuries which are permanent and lasting, physical pain and mental anguish, including diminished enjoyment of life and the need for revisions surgeries to repair and/or replace the device with the attendant risks of complications and death from such further surgeries.

177. The conduct of Defendants as described in this complaint was oppressive, intentional, reckless, and malicious, thus entitling Plaintiff to an award of punitive damages to punish and make an example of Defendants.

WHEREFORE, Plaintiff Jean D. Wright requests judgment against all Defendants, jointly and severally, for:

A. Compensatory damages in excess of $75,000, in an amount to fully compensate Plaintiff for all her injuries and damages, both past and present;

B. Compensation for non-economic damages, both past and present, including, but not limited to, past and future medical expenses, costs for past and future rehabilitation and/or home health care, permanent disability, including permanent instability and loss of balance, loss of enjoyment of life, and pain and suffering;

C. Restitution and disgorgement of all revenue that Defendants have obtained through the manufacture, marketing, sale and administration of the ATTUNE Device;

D. Punitive damages;

E. Attorney's fees and costs;

F. Pre-judgment interest;

G. Such other and further relief as the Court considers just and proper.

JURY DEMAND

Plaintiff demands a trial by jury on all issues so triable with the maximum number of jurors permitted by law.

Respectfully submitted,

/s/ John (Hui) Li

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